

WE CLAIM:

1. A method for diagnosing a cancer in a mammal, comprising:
detecting and measuring the hepsin gene copy number in a biological subject
5 from a region of the mammal that is suspected to be precancerous or cancerous, thereby
generating data for a test gene copy number; and

comparing the test gene copy number to data for a control gene copy number,
wherein an amplification of the gene in the biological subject relative to the control indicates
the presence of a precancerous lesion or a cancer in the mammal.

10 2. The method according to claim 1, wherein the biological subject is selected
from the group consisting of ovarian tissue, prostate tissue, breast tissue, and lung tissue.

3. The method according to claim 1, wherein the data is stored in an electronic or
a paper format, wherein the electronic format is selected from the group consisting of
electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory
15 chip, ROM or RAM, magnetic optical disk, tape, video, video clip, microfilm, internet,
shared network, shared server; wherein the data is displayed, transmitted or analyzed via
physical transfer, electronic transmission, video display, or telecommunication; wherein the
data is compared and compiled at the site of sampling specimens or at a location where the
data is transmitted.

20 4. A method for inhibiting cancer or precancerous growth in a mammalian tissue,
comprising contacting the tissue with a nucleotide molecule that interacts with hepsin DNA
or RNA and thereby inhibits hepsin gene function.

5. The method according to claim 4, wherein the nucleotide molecule is an
antisense nucleotide.

25 6. The method according to claim 4, wherein the nucleotide molecule is a
ribozyme.

7. The method according to claim 4, wherein the nucleotide molecule forms a
triple helix with a hepsin-encoding nucleic acid.

30 8. The method according to claim 4, wherein the tissue is selected from the group
consisting of ovarian tissue, prostate tissue, breast tissue, and lung tissue.

9. A method for monitoring the efficacy of a therapeutic treatment regimen in a patient, comprising:

measuring the hepsin gene copy number in a first sample of precancerous or cancer cells obtained from a patient;

5 administering the treatment regimen to the patient;

measuring the hepsin gene copy number in a second sample of precancerous or cancer cells from the patient at a time following administration of the treatment regimen; and

10 comparing the gene copy number in the first and the second samples, wherein data showing a decrease in the gene copy number levels in the second sample relative to the first sample indicates that the treatment regimen is effective in the patient.

10. The method according to claim 9, wherein the precancerous or cancer cells are obtained from ovarian tissue, prostate tissue, breast tissue, and lung tissue.

11. The method according to claim 9, wherein the data from measuring or
15 comparing the expression levels is stored in an electronic or a paper format, wherein the electronic format is selected from the group consisting of electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM or RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, shared server; wherein the data is displayed, transmitted or analyzed via physical transfer, electronic
20 transmission, video display, or telecommunication; wherein the data is compared and compiled at the site of sampling specimens or at a location where the data is transmitted.

12. A method for diagnosing a cancer in a mammal, comprising:

measuring the level of hepsin mRNA transcripts in a biological subject from a region of the mammal that is suspected to be precancerous or cancerous, thereby generating
25 data for a test level; and

comparing the test level to data for a control level, wherein an elevated test level of the biological subject relative to the control level indicates the presence of a cancer or precancerous lesion in the mammal.

13. The method according to claim 12 wherein the biological subject is selected
30 from the group consisting of ovarian tissue, prostate tissue, breast tissue, and lung tissue.

14. The method according to claim 12, wherein the data is stored in an electronic or a paper format, wherein the electronic format is selected from the group consisting of electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM or RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, 5 shared network, shared server; wherein the data is displayed, transmitted or analyzed via physical transfer, electronic transmission, video display, or telecommunication; wherein the data is compared and compiled at the site of sampling specimens or at a location where the data is transmitted.

15. A method for inhibiting cancer or precancerous growth in a mammalian tissue, 10 comprising contacting the tissue with an inhibitor of hepsin protein or a fragment thereof.

16. The method according to claim 15, wherein the cancer or precancerous growth is metastasis.

17. The method according to claim 15, wherein the inhibitor is an antibody that binds to hepsin protein.

18. The method according to claim 15, wherein the inhibitor is an antagonist to hepsin protein. 15

19. The method according to claim 15, wherein the inhibitor is an antagonist to the protease activity of hepsin protein.

20. The method according to claim 15, wherein the inhibitor is a small molecule.

21. The method according to 15, wherein the tissue is selected from the group consisting of ovarian tissue, prostate tissue, breast tissue, and lung tissue. 20

22. A method for monitoring the efficacy of a therapeutic treatment regimen in a patient, comprising:

measuring at least one of hepsin mRNA or hepsin expression levels in a first 25 sample of precancerous or cancer cells obtained from a patient;

administering the treatment regimen to the patient;

measuring at least one of hepsin mRNA or hepsin expression levels in a second sample of precancerous or cancer cells from the patient at a time following administration of the treatment regimen; and

comparing at least one of hepsin mRNA or hepsin expression levels in the first and the second samples, wherein data showing a decrease in the levels in the second sample relative to the first sample indicates that the treatment regimen is effective in the patient.

23. The method according to claim 22, wherein the precancerous or cancer cells
5 are obtained ovarian tissue, prostate tissue, breast tissue, and lung tissue.

24. The method according to claim 22, wherein the data from measuring or
comparing the expression levels is stored in an electronic or a paper format, wherein the
electronic format is selected from the group consisting of electronic mail, disk, compact disk
(CD), digital versatile disk (DVD), memory card, memory chip, ROM or RAM, magnetic
10 optical disk, tape, video, video clip, microfilm, internet, shared network, shared server;
wherein the data is displayed, transmitted or analyzed via physical transfer, electronic
transmission, video display, or telecommunication; wherein the data is compared and
compiled at the site of sampling specimens or at a location where the data is transmitted.

25. An isolated hepsin gene amplicon, wherein the amplicon comprises more than
15 one copy of a polynucleotide selected from the group consisting of:

- (a) a polynucleotide encoding the polypeptide set forth in SEQ ID NO:2;
- (b) a polynucleotide set forth in SEQ ID NO:1;
- (c) a polynucleotide having at least about 90% sequence identity to the
polynucleotide of (a) or (b); and
- 20 (d) a polynucleotide that is overexpressed in tumor cells having at least about
90% sequence identity to the polynucleotide of (a) or (b).

26. The isolated amplicon of claim 25, which comprises a polynucleotide having
at least about 90% sequence identity to SEQ ID NO: 1.

27. The isolated amplicon of claim 25, which comprises a polynucleotide having
25 at least about 90% sequence identity to a polynucleotide encoding the polypeptide as set forth
in SEQ ID NO:2.

28. The isolated amplicon of claim 25, which comprises a polynucleotide having
at least about 95% sequence identity to a polynucleotide encoding SEQ ID NO:2.

29. The isolated amplicon of claim 25, which comprises a polynucleotide
30 encoding the polypeptide set forth in SEQ ID NO:2.

30. The amplicon of claim 25, wherein the polynucleotide comprises SEQ ID NO:1.

31. The amplicon of claim 25, wherein the polynucleotide sequence encodes the polypeptide of SEQ ID NO:2.

5 32. A method of making a pharmaceutical composition comprising:

- a) identifying a compound which is a modulator of hepsin;
- b) synthesizing the compound; and
- c) optionally mixing the compound with suitable additives.

33. A method for diagnosing a cancer in a mammal, comprising:
10 detecting hepsin protein expression by contacting a biological subject from a region of the mammal that is suspected to be precancerous or cancerous with anti-hepsin antibody, thereby generating data for a test level; and

comparing the test level to data for a control level, wherein an elevated test level of the biological subject relative to the control level indicates the presence of a cancer or precancerous lesion in the mammal.
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34. The method according to claim 33, wherein the biological subject is selected from the group consisting of ovarian tissue, prostate tissue, breast tissue, and lung tissue.

35. The method according to claim 33, wherein the data is stored in an electronic or a paper format, wherein the data is stored in an electronic or a paper format, wherein the electronic format is selected from the group consisting of electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM or RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, shared server; wherein the data is displayed, transmitted or analyzed via physical transfer, electronic transmission, video display, or telecommunication; wherein the data is compared and
20 compiled at the site of sampling specimens or at a location where the data is transmitted.
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36. A method of modulating hepsin activities by contacting a biological subject from a region that is suspected to be precancerous or cancerous with a modulator of the hepsin protein.

37. A method according to claim 36 wherein the modulator is a small molecule.

30 38. A method according to claim 36, wherein said modulator partially or completely inhibits transcription of hepsin.